MAR 1 4 2000

510(k) SUMMARY K K000675

MODEL HD-502
NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM

1. **COMPANY INFORMATION.** *Name:* Jawon Medical Co., Ltd.
   Address: 7F Jeong Ju Bldg., 1451-38 Seocho-Dong, Seocho-Ku, Seoul, Korea
   Phone: (011) 82-2-587-4056 *Contact:* Mr. Won-Hee Park, President

2. **DEVICE IDENTIFICATION.** *Trade Name:* Model HD-502 Manual Digital Blood Pressure Monitor
   Common Name and Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN

3. **PREDICATE DEVICE.** Model SE-600 Digital Blood Pressure Meter, Sein Electronics Co., Ltd. - K912588, SE decision 12/19/91.

4. **DEVICE DESCRIPTION.** *General:* The Jawon Model HD-502 is a compact digital blood pressure monitor intended for measurement of blood pressure at the brachial artery. The system uses the oscillometric method of operation. The plug-in type pneumatic cuff with built-in semiconductor strain gauge is manually inflated by squeeze bulb. The system is microprocessor controlled and includes pushbutton operating controls, circuitry to detect and process minute pressure oscillations; a six-digit LCD display of systolic and diastolic pressure readings and heart rate; and a memory function that stores the previous eight measurement results.
   Operation: If occlusion of the systolic pulse is not achieved by initial pressurization, a buzzer sounds to indicate a measurement fault, signalling the operator to manually increase cuff pressure until a proper systolic measurement can be obtained. The device employs a pressure measurement algorithm designed to detect, filter, process, and store pressure readings. In the event of excessive cuff pressure, the operator can initiate rapid exhaust immediately by pressing the button on the squeeze bulb.
   Power: The Model HD-502 is powered by four AA-size 1.5V batteries. Power is shut down automatically if the unit remains idle for a period of approximately two minutes.

5. **INTENDED USES.** The Model HD-502 system is indicated for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, age 18 and above. Because the device is recommended for use in a home care environment, use should be limited to patients capable of understanding written and/or oral directions.

6. **COMPARISON WITH PREDICATE DEVICE.** The Jawon device has been compared with the Sein Model SE-600 Digital Blood Pressure Meter. The intended use of the two systems is the same. The principle of operation (oscillometric measurement) and many operating features are identical. Both systems utilize a squeeze bulb for cuff inflation and maintain a constant bleed down rate during deflation and measurement through the use of an electronic air release valve. Both present measurement results digitally on a six-digit LCD and are powered by four 1.5V batteries. The principal differences are that the Jawon device offers a wider measurement range (20 to 320 mmHg as compared to the 20 to 280 mmHg pressure range of the Sein unit) and sufficient memory capacity for eight stored readings of previous measurement results as compared to the single measurement memory capacity of the Sein unit. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.

7. **PERFORMANCE DATA.** The measurement performance of the Jawon system has been evaluated in clinical studies conducted in accordance with ANSI/AAMI Standard SP10-1992 and found to comply fully with the accuracy criteria established in the standard. Safety testing including electrical characteristics of the system and components, life testing over 10,040 operational cycles, intra-device variability, environmental integrity under various operating and storage conditions including high and low altitude extremes, and resistance to vibration and shock has been conducted with satisfactory results. Similarly, electromagnetic compatibility compliance studies have been conducted by ONETECH Testing & Evaluation Laboratories, and the device was found to comply with all relevant standards. Software verification and validation have been performed. It is concluded that the subject device complies with all applicable safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2000

Jawon Medical Co., LTD.
c/o Ms. Carole Stamp
510(k) Program Manager
TUV Product Service Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K000675
Manual Digital Blood Pressure Monitor, Model HD-502
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: February 24, 2000
Received: February 28, 2000

Dear Ms. Stamp:

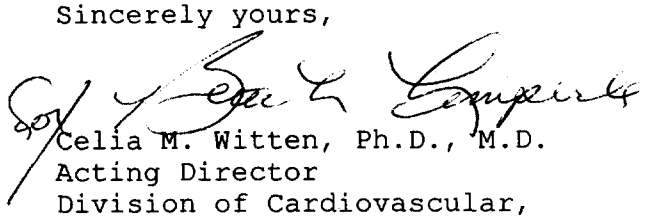
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

THIRD PARTY

K000675

510(k) Number (if known): K000675

Device Name: Noninvasive Blood Pressure Measurement System
Model HD-502 Manual Digital Blood Pressure Monitor

Indications For Use:

Noninvasive measurement of systolic and diastolic blood pressure and heart rate in adult patients, i.e., age 18 and above, in a home care environment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter B. Lamperg

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000675

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)